

NIH POLICY MANUAL

54518 - PEER REVIEW APPEALS

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1. Explanation of Material Transmitted: This chapter contains the policy and procedures that govern the handling of appeals of the peer review of NIH grant applications.

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A. Purpose:

This chapter describes the policy, procedures, and responsibilities for providing timely and appropriate NIH action and response when an applicant for an NIH grant expresses in writing concerns about the peer review of his/her application. This policy and the implementing procedures are applicable to all competing applications for all grant mechanisms.

B. Policy:

All appeals or other written expressions of concern about the peer review of competing grant applications shall be responded to in writing (not by electronic mail) within 10 working days of receipt. The response shall be handled

according to the procedures outlined herein, and shall be generated in a manner that preserves the applicant's right to confidentiality and does not jeopardize his/her future standing with reviewers, Councils, or staff. Where that response cannot be final, an interim written response that indicates that the matter is under examination shall be provided.

The response to an applicant must: (a) show that care was given to the examination of the issues; (b) be specific in explaining the Institute's or NIH's position about the issues; and (c) give the rationale for the ensuing decision/actions. When correspondence about competing applications is deemed to constitute an appeal, the response shall, at a minimum: (a) confirm that the issues raised by the applicant are acceptable as an appeal, and (b) indicate the timing and possible outcomes of the examination of the appeal in arriving at the Institute's final response.

All originals of correspondence on the matter received from the applicant and copies of NIH-originated correspondence to the applicant shall be placed in the official file for the application.

The result of an appeal is a decision regarding the applicant's expressed concerns and, if the concerns are valid, the actions necessary to resolve them. It is not a reversal or overturning of the recommendations of an SRG.

Funding decisions cannot be appealed through this system. Issues that may be appealed include aspects of the receipt, referral, and initial review of an application. Examples are:

1. **Receipt** - the acceptability of an application for review (excluding the refusal to accept applications that do not follow the published guidelines or instructions for submission);
2. **Referral** - assignment to a Scientific Review Group (SRG); assignment to an Institute as the potential awarding component;
3. **Initial Review** - the composition of an SRG or site visit team (including on the basis of scientific expertise, conflict of interest, and bias or prejudice); the findings and recommendations of SRGs or site visit teams. While differences of scientific opinion per se may not be appealed, scientific errors or other issues of process may be.

C. References:

1. OER Policy Announcement 1997-05 Revised, November 13, 1997.
2. NIH Guide, vol. 26, no. 38, November 21, 1997, "Appeals of Initial Scientific Peer Review."
3. NIH Manual 1743 "Keeping and Destroying Records"
4. NIH Manual 4304 "Receipt Dates for NIH Competing Grant and Fellowship Applications"

5. NIH Manual 4510 "Referral and Initial Review of NIH Grant and Cooperative Agreement Applications"
6. NIH Manual 4511 "Project Site Visits Involving Review of Grant and Cooperative Agreement Applications"
7. NIH Manual 4512 "Summary Statements"
8. NIH Manual 4513 "Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities"
9. NIH Manual 4514 "Role of Staff at Peer Review Advisory Committee Meetings and Exchange of Information Among Review, Program, and Grants Management Staffs"
10. NIH Manual 4515 "Guidelines for Dually Assigned Grant Applications"
11. NIH Manual 4516 "Review of Institutional National Research Service Award Applications"
12. NIH Manual 4517 "Review of Program Project Grant Applications"
13. NIH Manual 4815 "Implementation of Cooperative Agreements"

D. Definitions:

1. **Appeal** - a letter or other written document from an applicant received at any point in the peer review process (from receipt through the Council review) that, as judged by NIH staff, contests some aspect of the process for a competing application and, therefore, requires staff action.
2. **Appeals Officer** - the senior-level official not directly involved in peer review designated by the Institute Director to oversee appeal procedures and cases in the Institute. The Appeals Officer is not the person to be contacted directly by applicants in an appeal situation; the Program Administrator is the point of contact.
3. **Communication** - a letter or other written document from an applicant received at any point in the peer review process that, as judged by NIH staff, simply provides additional information or data, therefore, does not trigger the appeal process. Communications are often post-review, pre-Council requests for restoration of project funds and/or time or for high program relevance.
4. **Council** - the advisory committee of an Institute that provides the second level of peer review; also refers herein to a National Advisory Board or subcommittee of a Council or Board.
5. **Council Review** - the second step in the peer review process, in which a National Advisory Council evaluates an application in terms of both the adequacy of the initial review, and program and other considerations, and makes a funding recommendation to the Institute Director. Also refers to the examination and resolution of appeals by Councils.
6. **Deferral** - the administrative action of delaying the review of an application, usually because additional information is needed to complete the review or because the review has been compromised in some way.
7. **Initial Review** - the initial step in the peer review process, in which a

Scientific Review Group evaluates the scientific and technical merit of an application and produces a recommendation regarding further consideration of the application.

8. **Institute** - a funding component of the NIH; also refers herein to a Center.
9. **Peer Review** - the process by which an application for a grant is evaluated for potential funding. It encompasses the acceptance of the application for review, the assignments for initial review and for potential Institute funding, the initial scientific review, and the Council review. It does not include the decision to fund or not fund the application, which is made subsequent to the peer review process.
10. **Program Administrator** - the professional staff person in a funding Institute who is responsible for the scientific administration of an application, particularly after the initial review has been completed, and for the handling of any appeal contesting the review of the application.
11. **Scientific Review Administrator** - the professional staff person, either in the Center for Scientific Review (CSR) or an Institute, who is responsible for managing the initial scientific review of an application.
12. **Scientific Review Group** - an advisory committee of the CSR or an Institute (whether a standing committee or subcommittee or a Special Emphasis Panel [SEP]) that evaluates the scientific and technical merit of an application in accordance with established review criteria and procedures.

E. Responsibilities:

1. **CSR and the Institutes:** The Center for Scientific Review (CSR) is responsible for the handling and resolution of appeals received prior to initial review that concern (a) either the receipt or the assignment to an Institute for funding of all NIH applications and (b) the assignment to an SRG of applications to be reviewed by CSR. The Institutes are responsible for handling or resolving: (a) appeals received prior to the initial review concerning (1) the assignment to and composition of an SRG for those applications to be reviewed by an Institute SRG, and (2) the responsiveness of applications to RFAs issued by the Institute and (b) post-review appeals concerning initial review issues for all applications assigned to the Institute for funding. Any official whose direct actions are the subject of an appeal shall not decide the disposition of the appeal.
2. **Institute Directors:** Institute Directors have the authority and responsibility for designating a senior official as the Institute's Appeals Officer and for reviewing any appeals to be presented to the Council.
3. **Appeals Officers:** Appeals Officers have the responsibility for overseeing appeal procedures within the Institute, deciding which appeals will be presented to Council, and reviewing those appeals with the Director prior to the Council meeting.

4. **Program Administrators:** The Program Administrator assigned to the application, not the Scientific Review Administrator who managed the review, is the person responsible for providing guidance to an investigator who, having received the summary statement, wishes to contest the review. The Program Administrator may be able to provide additional information about the review or about program priorities that will help the investigator to decide either to revise the application by addressing the weaknesses identified or to reconsider the basic intent of the proposed project. As a result of this discussion and guidance, the investigator may decide to submit a revised or a new application. Such a decision will resolve the situation, and the need for a formal, written appeal will be eliminated. However, if the investigator chooses to document in writing concerns about the peer review of his or her application that are deemed to constitute an appeal, the Program Administrator has the responsibility for seeing that the appeal is dealt with in accord with the general procedures outlined herein, as implemented by the Institute.
5. **Scientific Review Administrators:** Scientific Review Administrators of applications whose initial review has been appealed have the responsibility for being available for consultation by program staff, consulting with their supervisor, and being available for comment at the Council meeting when the review staff position is contrary to that of program staff or the applicant, i.e., that the application should not be rereviewed.

F. Procedures:

Every Institute must have an internal administrative process to ensure that decisions on disputed issues and appeals are made at the appropriate Institute level and that the written response to the applicant reflects the official Institute position or decision. The Institute's Appeals Officer is responsible for this process.

The person or office to whom the incoming correspondence from an applicant is addressed may or may not have the primary responsibility for handling the issue raised. Nevertheless, all such incoming correspondence must be acknowledged in writing and, as appropriate, indicate the person to whom it has been referred for handling. The respondent must send the original of the incoming to the official file with documentation of his/her response.

1. **Acceptance:** Disputes of receipt and referral issues submitted before the initial review has taken place will be accepted beginning immediately after the assignments have been made. Disputes of responsiveness issues will be accepted immediately after the decision not to accept an application for review has been made. Appeals received after the initial review has taken place will be accepted during the period from

transmission of the summary statement up to 30 calendar days after the Council meeting.

2. **Handling:** Every effort should be made to resolve disputes of receipt and referral issues so that delay of the review is minimized.

- a. **Receipt, Referral, and Responsiveness Issues:** When issues of receipt or assignment to a funding component for any application or the assignment to an SRG for CSR-reviewed applications are contested before the initial review has taken place, they should be directed to the Chief of the CSR Division of Receipt and Referral, who may handle the matter directly or refer it the appropriate CSR Division Director.

When issues are raised for Institute-reviewed applications about assignment to an SRG or the responsiveness of an application to an RFA, they should be handled according to the procedures established by the Institute.

In all cases related to receipt, referral, and responsiveness, the appeal should be handled by evaluating the disagreement, determining whether corrective action is necessary, and conveying the decision to the applicant with an explanation of the reasons for the decision. That decision is final, and the pre-review disposition of the application may not be appealed further.

- b. **Initial Review Issues:** When issues are raised after the review has taken place about the initial review of an application, the following procedures should be followed.
 1. Submission and Initial Institute Response: If the investigator chooses to pursue an appeal, s/he should submit a letter that details his/her specific concerns about the review of the application to the Program Administrator, who will forward copies to the Appeals Officer and the SRA. Within ten working days of receiving the appeal, the Program Administrator should acknowledge its receipt in writing, indicating that a final decision will be communicated within 30 working days after either the Council meeting or the date the appeal letter was received (if too late to be presented to the Council at its meeting), whichever is later.
 2. Administrative Resolution: Some appeals can be resolved administratively through direct communication between the Program Administrator and the SRA. The Program Administrator will consult with his/her supervisor about the appeal, and with the SRA of the scientific review group that reviewed the application. who in turn will

consult with his/her supervisor. If all agree that the application should be deferred for re-review, the Program Administrator will notify the investigator, and the SRA will proceed with the re-review. The Appeals Officer must be notified of this resolution.

3. Applicant Decision to Resubmit and Withdraw Appeal: In cases where a formal appeal has been received and program and review staff agree that the review was not substantially flawed, the Program Administrator should share this information with the investigator and indicate that, in the end, it might be in his/her best interest to submit a new or a revised application, rather than pursue the appeal. If the investigator agrees with that guidance, s/he should submit a letter to the Program Administrator withdrawing the appeal. The Program Administrator will forward a copy of this letter to the Appeals Officer.
4. Review of Unresolved Appeals by Appeals Officer: In those cases where program and review staff do not agree on the resolution of an appeal or together they disagree with the investigator, the Program Administrator should submit a written recommendation on the disposition of the case to the Appeal Officer. The Appeal Officer will review the case, and will confirm which cases must be resolved by the Council. Prior to the Council meeting, the Appeal Officer will discuss all appeals that are to be presented for Council consideration with the Institute Director to insure his/her concurrence with the staff recommendation.
5. Resolution by Council: Appeals unresolved by staff or applicant action should be presented to the Council for its consideration. The Program Administrator and SRA should be available for the Council's discussion of the appeal so that they might answer any questions that arise. Council members should be assigned to review the appeal and be provided with the necessary documents (e.g., application, summary statement, appeal letter, Institute staff recommendation, and written comments from the SRA, if any).

The Council has two usual options with regard to appeals: (1) recommend that the application be re-reviewed, whether by the same or a different SRG, or (2) concur with the initial scientific review (thus, reject the appeal). Except under unusual circumstances, the Institute Director will accept the Council's recommendation, which will become the Institute decision on the appeal. In the

case of Center for Scientific Review (CSR)-reviewed applications where the Council recommendation for re-review is disputed by CSR, the Deputy Director for Extramural Research should be consulted for assistance with a final resolution.

When the Institute decision is to concur with the initial review (i.e., not to re-review the application), the investigator should be advised in writing of that decision by the Program Administrator or the Executive Secretary of the Council. This notification should inform the investigator that the decision is final, that there are no further avenues for administrative recourse, but that the appeal letter will be retained in the official file for the application.

G. Records Retention:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, "NIH Records Control Schedule." See manual for specific instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your ICD Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to members of Congress or Congressional committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significant periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

H. Management Controls:

The purpose of this manual issuance is to describe the policy, procedures, and responsibilities for providing timely and appropriate NIH action and response when an applicant for an NIH grant expresses in writing concerns about the peer review of his/her application.

Office Responsible for Reviewing Management Controls Relative to this Chapter: Through this manual issuance the Office of Extramural Research, Office of Extramural Programs is accountable for the method used to ensure that management controls are implemented and working.

Frequency of Review: On-going review.

Method of Review: The method used to maintain oversight and a system of internal controls ensuring effective implementation and compliance with this policy will be through: incorporation of training on the procedures into existing programs for the training of extramural scientist administrators, periodic publication of Notices about these procedures in the NIH Guide to Grants and Contracts, and periodic discussion with the Extramural Program Management Committee to ensure that management controls and intended program results are achieved.

Review Reports: The Peer Review Appeals process is a management control process in and of itself. When an applicant for an NIH grant expresses in writing concerns about the peer review of his/her application, a review is initiated and a decision is made in all cases (unless the appeal is withdrawn). No additional management review of the appeal system is deemed necessary.